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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,602	02/22/2005	John Hadden	3115.00066	4753

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EXAMINER	
JUEDES, AMY E	
ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
08/29/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/500,602	HADDEN ET AL.	
	Examiner	Art Unit	
	AMY JUEDES	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 June 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *24* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *24* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment and remarks, filed 6/28/11, are acknowledged.

Claim 24 has been amended.

Claim 24 is pending and is under examination.

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 24 stands rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,614,504, March 25, 1997.

As set forth previously, The '504 patent teaches a method of enhancing the immune response to a vaccine comprising administering an adjuvant formulation comprising inosine 5-monophosphate compounds, including MIMP (i.e. a protected IMP compound, see column 1, 6, 9, and, in particular). The '504 patent teaches administering the IMP compounds to treat influenza (see column 14, in particular). The '504 patent teaches measuring a response to the vaccine by performing proliferation assays in response to viral antigen (i.e. detecting a T cell response, see column 17, in particular). The '504 patent also teaches measuring an enhanced DTH response and T cell activation and cytokine secretion in response to IMP compounds (i.e. detecting a T cell response, see column 18-19, in particular).

Applicant's arguments filed 6/28/11 have been fully considered, but they are not persuasive.

Applicant argues that the '504 patent only disclosed administering an IMP compound alone or in combination with squalene, and does not disclose administering an influenza vaccine.

In Example 10, the '504 patent teaches treating with influenza virus in combination with MIMP. As recited in the instant claims, an influenza vaccine can be a "virus", as taught in the '504 patent. The '504 patent also teaches that MIMP can be administered in combination with a subinfection dose of influenza virus (i.e. a virus or "influenza vaccine") to protect form subsequent challenge with the virus (see column 17, in particular). The '504 patent also teaches administering MIMP as an adjuvant in

combination with any commercially available vaccine for treating viral infection, including influenza virus (see columns 16, in particular, as well as columns 4, 12, and 14). The '504 patent teaches that said influenza vaccines can be ineffective alone (see column 4, in particular). Thus, the '504 patent teaches embodiments that fall within the scope of the instant claims.

Applicant further argues that the '504 patent describes only a general T cell stimulation, and does not show a T cell response to influenza. Applicant concludes that without showing that IMP provides a T cell response specifically to influenza, the '504 patent does not disclose the method of the present invention.

The '504 patent teaches that after administration of viral vaccine combined with an IMP compound, proliferation assays in response to viral antigen can be performed in order to determine if the subject has been successfully immunized (see column 17, 5th full paragraph). It is well established that T cells proliferate in response to antigen stimulation in successfully immunized subjects, and the method disclosed by the '504 patent would inherently measure T cells proliferating specifically to the viral antigen. Moreover, the '504 patent teaches that MIMP acts to stimulate T cells and induce Th1 cells (see column 18, in particular).

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 24 stands rejected under 35 U.S.C. 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

As set forth previously, The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

A method of treating influenza comprising administering a protected IMP compound in combination with an antiviral agent, microbial agent, or vaccine agent, and detecting a "T cell response specific to influenza".

Applicant indicates that support for the new limitations of can be found in paragraph 68 and in Examples 2-4 of the specification.

A review of the specification fails to reveal support for the new limitations.

In examples 2-4, the specification discloses administering a flu vaccine in combination with MIMP and measuring an influenza specific T cell response. However, the instant claims are not limited to administering an influenza vaccine in combination with MIMP and measuring a T cell response to influenza. Rather the claims broadly encompass administering MIMP with any vaccine agent, antiviral agent, or antimicrobial agent. For example, the claims specifically set forth that MIMP is administered in combination with parasite, for treating influenza and inducing influenza specific T cell responses. The specification does not disclose administering a parasite vaccine agent for treating influenza and for inducing detectable influenza specific T cell responses, as claimed.

Applicant's arguments filed 6/28/11 have been fully considered, but they are not persuasive.

Applicant argues that Example 4 discloses measuring a T cell response after administration of MIMP and an influenza vaccine.

In example 4, the specification discloses treating influenza comprising administering a influenza vaccine comprising influenza peptide/protein, in combination with MIMP and measuring an influenza specific T cell response. However, the claims, as amended, define the influenza vaccine to be much broader in scope than what is disclosed by the instant specification. For example, the claims recite that the influenza vaccine can be a parasite. As noted above, the instant specification does not disclose an influenza vaccine that is a parasite, nor treating influenza and inducing influenza specific T cells with a parasite.

5. No claim is allowed.

6. **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E. Juedes, whose telephone number is 571-272-4471. The examiner can normally be reached on 8am to 4:30pm, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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